will be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

(b) The initial listing of devices and subsequent June and December updatings shall be on form FDA–2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FDA–2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FDA–2892, tapes for computer input or hard copy computer output may by submitted if equivalent in all elements of information as specified in form FDA–2892. All formats proposed for use in lieu of form FDA–2892 require initial review and approval by the Food and Drug Administration.''

(c) The listing obligations of the initial importer are satisfied as follows:

(1) The initial importer is not required to submit a form FDA-2892 for those devices for which such initial importer did not initiate or develop the specifications for the device or repackage or relabel the device. However, the initial importer shall submit, for each device, the name and address of the manufacturer. Initial importers shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the initial importers; and

(2) The initial importer shall update the information required by paragraphs (c)(1) of this section at the intervals specified in § 807.30.

[43 FR 37997, Aug. 25, 1978, as amended at 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 69 FR 11311, Mar. 10, 2004; 69 FR 18473, Apr. 8, 2004; 69 FR 25489, May 7, 2004]

§ 807.25 Information required or requested for establishment registration and device listing.

(a) Form FDA–2891 and Form FDA–2891(a) are the approved forms for initially providing the information required by the act and for providing annual registration, respectively. The required information includes the name and street address of the device establishment, including post office code, all trade names used by the establishment, and the business trading name of the owner or operator of such establishment.

(b) The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing devices.

(c) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment he registers and to furnish this information to the Food and Drug Administration upon request.

(d) Each owner or operator shall provide the name of an official correspondent who will serve as a point of contact between the Food and Drug Administration and the establishment for matters relating to the registration of device establishments and the listing of device products. All future correspondence relating to registration, including requests for the names of partners, officers, and directors, will be directed to this official correspondent. In the event no person is designated by the owner or operator, the owner or operator of the establishment will be the official correspondent.

(e) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the act.

(f) Form FD–2892 is the approved form for providing the device listing information required by the act. This required information includes the following:

(1) The identification by classification name and number, proprietary name, and common or usual name of each device being manufactured, prepared, propagated, compounded, or processed for commercial distribution that has not been included in any list

of devices previously submitted on form FDA–2892.

(2) The Code of Federal Regulations citation for any applicable standard for the device under section 514 of the act or section 358 of the Public Health Service Act.

(3) The assigned Food and Drug Administration number of the approved application for each device listed that is subject to section 505 or 515 of the act.

(4) The name, registration number, and establishment type of every domestic or foreign device establishment under joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled.

(5) Whether the device, as labeled, is intended for distribution to and use by the general public.

(6) Other general information requested on form FDA–2892, i.e.,

(i) If the submission refers to a previously listed device, as in the case of an update, the document number from the initial listing document for the device,

(ii) The reason for submission,

(iii) The date on which the reason for submission occurred,

(iv) The date that the form FDA–2892 was completed,

(v) The owner's or operator's name and identification number.

(7) Labeling or other descriptive information (e.g., specification sheets or catalogs) adequate to describe the intended use of a device when the owner or operator is unable to find an appropriate FDA classification name for the device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37998, Aug. 25, 1978; 58 FR 46523, Sept. 1, 1993; 64 FR 404, Jan. 5, 1999; 66 FR 59160, Nov. 27, 2001; 69 FR 11312, Mar. 10, 2004]

§ 807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in § 807.3(c) shall be submitted on Form FDA–2891(a) at the time of annual registration, or by letter if the changes occur at other times. This information shall be submitted within 30 days of such changes. Changes in the names of officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

[69 FR 11312, Mar. 10, 2004]

§ 807.30 Updating device listing information.

(a) Form FDA–2892 shall be used to update device listing information. The preprinted original document number of each form FDA–2892 on which the device was initially listed shall appear on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows:

(1) If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator, then the owner or operator must submit form FDA–2892 containing all the information required by § 807.25(f).

(2) If an owner or operator discontinues commercial distribution of all devices in the same device class, i.e., with the same classification name, the owner or operator must submit form FDA–2892 containing the original document number of the form FDA–2892 on which the device class was initially listed, the reason for submission, the date of discontinuance, the owner or operator's name and identification number, the classification name and number, the proprietary name, and the common or usual name of the discontinued device.

(3) If commercial distribution of a discontinued device identified on a form FDA–2892 filed under paragraph (b)(2) of this section is resumed, the owner or operator must submit on form FDA–2892 a notice of resumption containing: the original document number of the form initially used to list that device class, the reason for submission,